UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,411	09/28/2006	Martin T. Lowy	PB60808	8514

20462 7590 12/26/2008

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
CRUZ, KATHRIEN ANN	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
12/26/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/599,411	LOWY, MARTIN T.	
	Examiner	Art Unit	
	KATHRIEN CRUZ	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/28/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 5-8 are presented for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of bipolar disorder with the administration of Tanetant as the NK_3 antagonist does not reasonably provide enablement for the **prevention** of bipolar disorder or enablement for **any** NK_3 antagonist.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: Claim 1 is drawn to a method of treating or **prevention** bipolar disorders by administering an effective amount of a NK_3 antagonist.

Breadth of the claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass prevention of neurological disorders in mammals which have potentially many different and pathogenesis of bipolar disorders are not known, although a number of hypotheses have been advanced. One hypothesis is that motor neurons, made vulnerable through either genetic predisposition or environmental factors. Each of these defects may or may not be addressed by the administration of the claimed compounds. Applicants claim that not only can bipolar disorders be treated with **any** NK_3 antagonist, but that it can also be **prevented** with an effective amount of **any** NK_3 antagonist.

Guidance of the Specification/Working Examples: Applicant has provided no guidance showing the actual "prevention" with prophylactic treatment of bipolar disorders. All the guidance are directed to the treatment of bipolar disorders with only Tanetant as the rather than the prevention.

State of the Art: *While the state of the art is relatively high with regard to the **treatment of the*** symptoms of ALS, the state of the art with regard to **prevention** of such disorders is underdeveloped. The state of the art, (Cho et al, U.S. Patent 6,068,846) teaches that there is no panacea for treating mood or mental disorder (column 2, lines 61-63), therefore it is highly speculative that a bipolar is preventable with the treatment of **any** NK_3 antagonist as claimed.

Predictability/Unpredictability in the Art: There *is a general lack of predictability in the pharmaceutical art. In re Fisher, 427, F. 2d 833, 166, USPQ 18 (CCPA 1970). It would be unpredictable for the skilled artisan to use the claimed formulation to prevent all forms of a central nervous system disorder such as amyotrophic lateral sclerosis (ALS) because of the reasons stated above.*

The Quantitation of Experimentation Required: In order to practice Applicants invention, it would be necessary for one to conduct an exhaustive amount of experiments. Applicant would need to provide reasonable data showing that **any** NK_3 antagonist can **prevent** bipolar disorders. Therefore, in order to practice the claimed invention, the amount of experimentation required would be considered undue and burdensome.

According, the method of **preventing** bipolar disorders with an effective amount of **any** NK_3 antagonist is not enabled by the instant specification. Thus, applicants are only enabled for Tanetant as the NK_3 antagonist.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States .

Claims 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Emonds-Alt et al (U.S. Publication 6, 420, 388) of record.

Emonds-Alt et al teaches that antagonist of the human NK_3 receptor which are useful for the treatment of disorder associated with dysfunction of the dopaminergic and noradrenergic systems (column 1, lines 28-31). Emonds-Alt et al teaches a method of treatment of bipolar disorders with the administration of osanetant (which is a NK_3 antagonist) (claims 1 and 7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emonds-Alt et al (U.S. Publication 6, 420, 388) as applied to claims 5 and 8 above, and further in view of Guttuso, JR (U.S. Publication 2002/0016283).

Applicant claims a method for preventing or treating bipolar disorder by administering an effective amount of NK_3, specifically talnetant.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Emonds-Alt et al cited as above.

Guttuso teaches talnetant hydrochloride is an NK_3 receptor antagonist (paragraph 0038). Guttuso teaches that talnetant may be used as an inhalation (paragraph 0028).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

The difference between the instant application and Emonds-Alt et al is that Emonds-Alt does not teach the specifically disclose talnetant as the NK_3 antangonist or the method of administration is in the form of "free base". This deficiency in Emonds-Alt is cured by the teachings of Guttuso.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Emonds-Alt because talnetant is an NK_3 receptor antagonist as taught by Guttuso.

One of ordinary skill in the art would have been motivated to do this because the administration of NK_3 receptor antagonist is known for the effective treatment of bipolar disorders.

With regards to talnetant in the form of free base, this would encompass administration of talnetant by means of inhalation which would be routine by one skilled in the art.

Summary

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 5-8 are rejected.

No claims allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Mon - Thurs 7:00am - 5:00pm with every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000 .

/KATHRIEN CRUZ/
Examiner, Art Unit 1617

/Rita J. Desai/

Primary Examiner, Art Unit 1625